c.) Remarks

Claims 8, 9 and 13 are amended to recite the present invention with the specificity required by statute and new claim 55 is presented. Claim 55 corresponds to previous claim 52, now rewritten in independent form. Additionally, the specification has been amended to correct a typographical error. Accordingly, no new matter has been added.

Claims 8 and 13 are rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter since the Examiner contends the "transformant" recited therein could include humans. In response, at least as to claim 13, this rejection is plainly without basis in law. That is, there is no statutory or constitutional prohibition against inclusion of humans in claimed processes -- it is well-understood that all process claims restrict activity in humans[1]. Nonetheless, simply to reduce the issues and expedite prosecution, these claims have both been amended to recite "non-human".

Claims 18 and 19 are rejected under 35 U.S.C. §101 as also being directed to non-statutory subject matter since the Examiner contends the "enzyme source" recited therein could include humans. Again, as discussed before with reference to claim 13, the Examiner's rejection has no basis in law. Moreover, as to this rejection there is also no basis in fact as well. That is, the enzyme source in claims 18 and 19 plainly cannot be a human; claims 18 and 19 each specifies the enzyme source is a polypeptide according to claims 2, 48 or 49. Claim 2 recites an isolated polypeptide consisting of SEQ ID NO:1. Claim 48 recites an isolated polypeptide comprising amino acids 31-310 of SEQ ID NO:1.

[1] Whether it be, e.g., a method of metabolizing, a method of promoting hair growth or a method of conducting business.

Claim 49 recites an isolated polypeptide comprising SEQ ID NO:1. Applicants are unaware of any claim construction as to how a human could possibly read on the term "isolated polypeptide". Accordingly, withdrawal of this rejection is respectfully requested.

Claims 18 and 19 also stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the present invention since the Examiner contends it is unclear "whether microorganisms, animal cells or plant cells or even entire animals or plants are contemplated as 'enzyme source'". In this regard, the Examiner's attention is respectfully invited to the foregoing discussion concerning these claims and their analyses under 35 U.S.C. §101 in which Applicants explained humans cannot be read upon the term "isolated". By the very same analysis, neither can any of microorganisms, animal cells, plant cells, entire animals or entire plants be properly read upon that term, either. Accordingly, this rejection too should be withdrawn.

Claims 9, 13-16, 20-24, 38 and 54 are rejected under 35 U.S.C. §112, first paragraph, because the Examiner states it would require undue experimentation to transform a non-human animal or a transgenic plant.

In response, solely in order to reduce the issues and expedite prosecution herein, "transgenic plant" has been deleted from claim 9 and claim 22 has been cancelled. As to the Examiner's objection to inclusion of transgenic animals, however, such rejection is respectfully traversed as being without basis in fact. Those of ordinary skill in the art has the ability to use the gene coding for the enzyme of the present invention to construct a non-human transgenic animal and produce the enzyme and reaction products based on the description in the specification and the knowledge in the art, as explained below.

Prior to the filing date of this application, many documents showed construction of transgenic animals transformed with a gene coding for glycosyltransferase (including galactosyltransferase). The following documents provide representative examples exemplifying such knowledge.

- Journal of Biological Chemistry, Vol. 269, No. 40 (1994), pages 25165-25171
- The Journal of Cell Biology, Vol. 126, No. 6 (1994), pages 1573-1583
- Development, Vol. 122 (1996), pages 2859-2872
- Frontiers in Bioscience, Vol. 1 (1996), pages 34-41

Further, it is also well-known that active oligonsaccharides are produced in milk, e.g., of a mouse transformed with a glycosyltransferase gene, as described below.

- Journal of Biological Chemistry, Vol. 270, No. 49 (1995), pages 29515-29519

Therefore, the record is clear that those of ordinary skill could readily transform a non-human animal with a gene encoding glycosyltransferase.

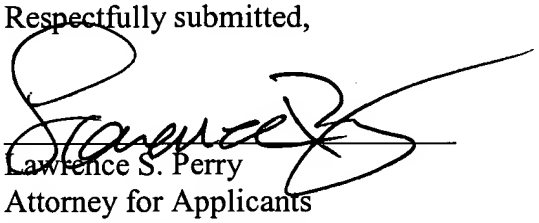
Accordingly, this rejection too is overcome and withdrawal thereof is earnestly solicited. Of course, if the Examiner is aware of some reason these articles are technically deficient or to be disregarded, then he is respectfully requested to provide Applicants with a personal affidavit in conformity with MPEP §2144.03 in the next Patent Office communication.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 2, 5-21, 23-25, 29-31, 33, 38, 48, 49 and 53-55 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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